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PHARMACEUTICAL COMPOSITIONS COMPRISING NATURAL HUMAN α-INTERFERON

This application is a United States national stage application based on International Application No. PCT/IT97/00040, filed February 27, 1997, which claims priority to Italian Patent Applications Nos. RM96A000136 filed February 28, 1996 and RM96A000247 filed June 14, 1996.

[0001] The invention concerns pharmaceutical compositions for a peroral administration comprising natural human α-interferon isolated from lymphoblastoid or leukocytic cells. In particular compositions are useful for therapy of viral infections, in particular viral hepatitis, neoplasia and immunodeficiency syndromes. The effective doses of interferon are clearly lower than dosages utilized for parenteral administration.

[0002] α-, β-, γ- interferons are usually administered by injection and are used for therapy. α - interferon is the most largely utilized interferon (1). In an updated study of medicaments for either acute or chronic viral hepatitis therapy (2), only α-interferon is widely accepted as a single therapeutic agent.

[0003] "Viral hepatitis" means at least five different pathologies, having different causative agents and designated hepatitis A, B, C, D, or E.

[0004] The therapeutic trend is to treat said pathologies with α-interferon, with dosages according to the kind of hepatitis, to the overall status of the subject and to other variable factors. In general, further to the interferon treatment an almost normalization in clinical and biochemical parameters is achieved for chronic hepatitis (B,C, or D). The effect of interferon on acute hepatitis has not been determined yet, although for hepatitis C, a therapeutic treatment with α-interferon lowers the chronicity of the disease.

[0005] Therapeutic cycles consist of alternate day subcutaneous administration of recombinant α-interferon (r α-IFN) at dosages of approximately 5,000,000 UI, that in special cases can be up to 9,000,000 UI/day.

[0006] The length of therapeutic cycles is from six months up to one year (nine months average).

[0007] In many cases, undesired side effects interfere with the course of therapeutic treatment. In fact some patients, in particular those at an advanced stage of disease or with severe physiologic damage, do not tolerate the therapy and therefore the